

**REMARKS**

A. Summary of the Invention and Claim Amendments.

Claims 1 and 12 are currently amended. Claims 5-11, 17-31 and 33-41 were previously canceled. After amendment, Claims 1-4, 12-16, 19, 21, and 32 are pending.

The claimed invention provides the art with the discovery that fatty acid esters, such as isopropyl myristate, can be used to rapidly kill ectoparasites as the *sole* ectoparasitidal agent; i.e., without application of other pediculocidal agents such as alcohol (per the Singer reference), without an *ectoparasiticidal amount* of a siloxane (versus, per dependent claims 8 and 10, as well as 19 and 21 as a mere non-active carrier), and without use of insecticides.

A. Response to Rejection under Section 103(a), based on Singer

Claims 12-15 stand rejected under Section 103(a), based on Singer, U.S. Patent No. 4,147,800.

The Office Action asserts that Singer teaches the use of isopropyl myristate (IPM) to kill ectoparasites at concentrations of 50 or 70%, and that it would have been obvious to one of ordinary skill in the art to omit alcohol from the Singer composition to avoid sensitivity thereto. However, such a teaching is not only entirely absent from Singer, the asserted reading of the reference contradicts what Singer does teach; i.e., that IPM is not effective except at toxic levels, and that it can only be effective when used in conjunction with an alcohol.

According to Singer, the alcohol is a necessary active that acts synergistically with IPM to enhance its activity:

**[00007] The pediculicidal toxicant of the instant invention is an admixture of an aliphatic alcohol and an aliphatic ester.** The combination is synergistic and retains its high level of activity when diluted in an inert pharmaceutically acceptable carrier, most notably an aqueous carrier.

To this end, Singer requires that an aliphatic alcohol be present in a concentration of at least 20% w/w as an active agent:

**[00012].... It has been found that an effective pediculicidal toxic amount can be obtained when the amount of the aliphatic alcohol in the treating composition is at least about 20 percent by weight and the amount of the aliphatic ester is at least about 15 percent by weight.**

In contrast, IPM alone below the purportedly toxic level of 70% w/w is described as being *ineffective* to kill 100% of lice as presently claimed (see, Col. 4, lines 21-32). Rather, as shown in the Figure of Singer, only about 15% of lice at most could be killed using IPM at lesser concentrations absent co-administration of an aliphatic alcohol (as an active agent, not merely an optional additive), as precluded in the present invention. Such a modest kill is explicitly described by Singer as not qualifying as an effective treatment:

**[00012] The alcohol-ester admixture is incorporated into the composition used to treat the substrate in need of such treatment, believed to be in need of such treatment, or desired to be prophylactically protected in an effective pediculicidal toxic amount. By such amount is meant the amount which will cause virtually 100% of the lice exposed in the two or four minute immersion test described below to die within 24 hours.**

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In short, Singer teaches that IPM alone is only effective to kill more than a minimal number of lice in an infestation if (a) used at a “toxic” level greater than 70% w/w; or (b) admixed with an aliphatic alcohol as a synergistic active agent, and (c) that, in either event, such effects would not be seen at less than about 24 hours following treatment.

Based on the foregoing arguments and previous amendments, Applicants have submitted that the claimed invention is not obvious over Singer. Applicants’ arguments are acknowledged in the current Office Action. However, it is asserted that the claims as previously presented could be read to encompass a situation where application of the claimed method resulted in no ectoparasites being killed at all; i.e., a null set of zero. While Applicants disagree that the claims, directed to killing ectoparasites, could be reasonably read as not doing so, the claims have now been further amended to clarify the point by reciting that at least 82% of ectoparasites treated will in fact die within the hour following a 10 minute long treatment.

Nothing in Singer suggests that such a result could be obtainable at all, much less through treatment of lice with concentrations of IPM lower than the over 70% concentration that Singer teaches is essential to killing lice in the absence of a co-administered aliphatic alcohol. As such, for all of the reasons above and as previously discussed, Applicants respectfully submit that the invention as claimed is not anticipated by Singer. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Response to Rejection under Section 103(a), based on Singer in view of Reid and further in view of Von Bittera.

Claims 12-16 and 32 stand rejected under Section 103(a), based on Singer in view of Reid, U.S. Patent No. 5,972,987 and further in view of Von Bittera, U.S. Patent No. 4,544,547.

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The Singer reference is discussed above. Reid is cited in combination with Singer only for its teaching with respect to use of a comb. It does not cure any of the deficiencies of the Singer reference noted above.

The von Bittera reference adds nothing of substance to the rejection. Contrary to its description in the Office Action, the reference does not teach any ectoparasiticidal use of IPM. To the contrary, IPM is mentioned only for optional use as a spreading agent, a conventional use for IPM and other fatty acid esters in topical compositions, including many beauty products (see, e.g., Col. 9, lines 9-37). As a spreading agent, concentrations of IPM are suggested for use in von Bittera that fall below the concentrations required by the present claims (*ibid*, at lines 36-39—note that the concentrations are described relative to that of a polyurethane component that forms the bulk of the compositions disclosed by von Bittera). As such, the reference lacks any suggestion or teaching for ectoparasiticidal use of IPM.

Further, von Bittera teaches directly away from the invention by requiring use of insecticides as ectoparasiticidal agents (see, e.g., Col. 3, lines 22-49, ectoparasitidal agents to be used in von Bittera's invention are either carbamates or pyrethroids). As such, the reference additionally lacks any suggestion, teaching or motivation of any kind to use IPM by itself as an ectoparasitidal agent.

Therefore, even when combined with Singer and Reid, the combination including von Bittera does not make the invention obvious. To the contrary, by virtue of teaching a conventional use of IPM as a spreading agent for an insecticide, von Bittera renders the invention's use of a higher concentration of IPM as the sole ectoparasiticidal agent *less* obvious.

Reconsideration and withdrawal of Claims 12-16 and 32 are rejected under Section 103, based on Singer in view of Reid and further in view of Von Bittera, is therefore respectfully requested.

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### CONCLUSION

All of the pending claims (1-4, 12-16, 19, 21, and 32) are believed to be in condition for allowance. In particular, Claims 1-4 and 16 appear to be free of any stated claim rejections and so are believed to be allowable. Further, the rejections stated as to Claims 12-15, and 32 are believed to be overcome for all of the foregoing reasons.

Reconsideration of those claims rejections and allowance of all pending claims is therefore respectfully requested.

No fees are believed to be due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,

  
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